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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,863	12/15/2003	Lee R. Brettman	079259-0237	5328

23630 7590 10/01/2010

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
10/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/735,863	BRETTMAN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,11-13,18,22,26,31,36,40,41,46,51,55-57,60,61,66-76,78,80-87,90-96 and 98-107.* is/are pending in the application.

4a) Of the above claim(s) *61,66-72,84-87,90-92 and 98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-13,18,22,26,31,36,40,41,46,51,55-57,60,73-76,78,80-83,93-96 and 99-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/10 has been entered.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1,11-13,18,22,26,31,36,40,41,46,51,55-57,60,73-76,78,80-83,93-96,99-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponath et al. (WO 98/06248) in view of Gordon et al. or Gordon et al. Applicants arguments have been considered and deemed not persuasive.

Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims (see claim 45, pages 6,28-30, Figures 11 and 12). Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation (see page 29, second paragraph). Ponath et al. disclose the antibody can be administered in

multiple doses (see page 29, second paragraph). Ponath et al. teach that said patient can additionally received steroids or sulfasalazine (see page 30) or other immunosuppressive agents wherein 6-mercaptopurine is an art known immunosuppressive agent. Ponath et al. do not disclose the particular claimed administration protocols. The Gordon et al. references disclose that patients with inflammatory bowel disease or ulcerative colitis can be treated with a dose of 3 mg of humanized antibody against an alpha4 integrin (see entire reference) wherein said dosage is a starting point for future clinical studies. Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation (see page 29, second paragraph). A routineer would have started with the 3 mg/kg dosage disclosed by Gordon et al. and arrived at the claimed protocols using routine experimentation. The functional characteristics of claims 22/26/40/41 would have been achieved with the starting dosage of 3 mg/kg (see claims 31/46). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims and that the dosage and schedule of administration used would be determined using routine experimentation whilst the Gordon et al. references disclose that patients with inflammatory bowel disease or ulcerative colitis can be treated with a dose of 3 mg of humanized antibody against an alpha4 integrin wherein said dosage is a starting point for future clinical studies and a routineer would have started with the 3 mg/kg dosage disclosed by Gordon et al. and arrived at the claimed protocols using routine experimentation. One of ordinary skill in the art would have been motivated to do the aforementioned because Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation whist Gordon et al. references disclose that patients with inflammatory bowel disease or ulcerative colitis can be treated with a dose of 3 mg of humanized antibody against an alpha4 integrin wherein said dosage is a starting point for future clinical studies. Furthermore, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize

that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill".

Regarding applicants comments, Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims. Thus, Ponath et al. have *already established* that ulcerative colitis can be treated with humanized LDP-02 antibody. In addition, Ponath et al. teach *a dose range* that encompasses the dosages recited in the claims (see page 29, lines 29-30). Thus, there is no unexpected result regarding the use of humanized LDP-02 antibody to treat ulcerative colitis because Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims. Regarding applicants comments about the references AV5 and AW5, there is no unexpected result regarding the use of humanized LDP-02 antibody to treat ulcerative colitis because Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims. Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation (see page 29, second paragraph).

In view of the fact that treatment of ulcerative colitis with humanized LDP-02 antibody was already known in the art, it would have required nothing more than routine experimentation to establish the preferred dosage. Regarding applicants speculation about what was routine in the art, the MPEP section 716.01(c) [R-2] states:

>II. < ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Regarding applicants comments about Table 25 and various other cited publications and unexpected results, Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims. Thus, it was already known in the art that ulcerative colitis could be treated with LDP-02 antibody. The various cited publications merely confirm the teachings of Ponath et al. that ulcerative colitis can be treated with

humanized LDP-02 antibody. Furthermore, as per the Feagen et al. NEJM reference, it is noted that the patients used in the study only represent a *subset of ulcerative colitis* patients (see page 2500, second column) wherein said studies are not necessarily germane to the entire patient population encompassed by the claimed methods.
Furthermore, Feagen et al. disclose that is *unclear as to whether their antibody is actually preferable to the use of natalizumab* (aka ANTEGREN) for treatment of ulcerative colitis (see page 2506, first column, first complete paragraph). Thus, Feagen et al. also establish that a comparison of the efficacy of natalizumab versus the claimed antibody is not possible in the absence of a single clinical trial which compares the efficacy of said antibodies in the same study using the same patient population.
Regarding applicants comments about Gordon et al., whilst the reference does not disclose use of the same antibody, it is merely cited as providing a starting point for antibody dosages to be used for the invention disclosed by Ponath et al. wherein both references relate to treatment of inflammatory bowel disease/ulcerative colitis using anti integrin antibodies. It is also noted that Feagen et al. disclose that is unclear as to whether their antibody is actually preferable to the use of natalizumab (aka ANTEGREN) for treatment of ulcerative colitis (see page 2506, first column, first complete paragraph). In addition, Fedyk et al. also conclude that is unclear if the claimed antibody will have an improved clinical result when used in patients (see last sentence). Regarding Feagen et al., said reference indicates that the "promising profile" will be further addressed in Phase 3 trials. As per above, Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody. Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation (see page 29, second paragraph). The MPEP section 2144.05 states:

II. OPTIMIZATION OF RANGES
A. Optimization Within Prior Art Conditions or Through Routine Experimentation
Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. ***"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."*** *In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955) (Claimed process which was performed at a temperature*

between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Regarding applicants comments, Fedyk et al. (P-0144) discloses:
"Clinical studies of vedolizumab are currently underway to confirm that selective inhibition of lymphocyte trafficking to the gastrointestinal tract without systemic immunosuppression confers an improved clinical risk to benefit profile for patients with UC or CD.".
Thus, Fedyk et al. (P-0144) indicates that is **currently unknown** how vedolizumab will perform compared to other agents used to treat IBD in humans. A potential therapeutic agent is always clinically evaluated according to risks and efficacy. Fedyk et al. (P-0025) also provides no information regarding the use of the recited antibody in comparison to other treatments for IBD. Furthermore, Fedyk et al. (P-0144) indicates that there are other art known treatments for IBD (such as TNF-alpha antagonists) wherein there is no evidence of record regarding the use of said agents in comparison to the claimed invention. Fedyk et al. (P-0144) also appears to use dosages that are outside those recited in the claims under consideration. In addition, there is no disclosure in Fedyk et al. (P-0025) of the parameters used to select the patients used in the study or information regarding other treatments that the patients may have received.

4. No claim is allowed.

5. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644